K081945 JUL 15 2008

510(k) Summary

Submitted by: Westmed, Inc.
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Date Prepared: June 30, 2008

Proprietary Name: AccuFlo & AccuFlux

Common Name: Non-electrically Powered Disposable Infusion Pump

Classification Name: Elastomeric External Infusion Pump (21 CFR 880.5725) 80 MEB

Predicate Device:

McKinley Accufuser	K050770	cleared April 14, 2005
Baxer Infuser	K062457	cleared September 21, 2006
MPS MedFlo	K052451	cleared December 8, 2005
I-Flow	K052117	cleared September 9, 2005

Device Description: The AccuFlo & AccuFlux models are both disposable, non-electric infusion pumps that deliver precise volume of medication at predetermined flow rate for IV therapy.

Intended Use of Device: AccuFlo & AccuFlux devices are intended for patients requiring intravenous, percutaneous, subcutaneous, intra-operative sites or epidural administration of medications. It is the responsibility of the user to ensure that the medication is prepared and administered accordance with the drug manufacturer's package insert.
The devices deliver controlled amounts of medication directly to the intraoperative site for pain management and/or antibiotic administration. The devices infuse the medication at an hourly flow rate. Medications are infused intraoperatively and postoperatively through intramuscular or subcutaneous routes
The devices are also intended for controlled delivery of local anesthetics in close proximity to nerves for post operative regional anesthesia and pain management. Routes of administration may be intraoperative or percutaneous.

Technological Characteristics: The proposed device is equivalent to the identified predicate devices with respect to technological characteristics and function. The device has been designed to comply with the applicable sections of International Electrotechnical Commission Standards for Medical Devices, IEC 60601-2-24, IEC 60601-1-1, IEC 60601-1-6, plus International Standards Organization Standards for Biocompatibility ISO 10993, Packaging ISO 11607, Ethylene Oxide Sterilization and Risk Management ISO 14971.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Westmed, Incorporated
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

JUL 15 2008

Re: K081905
Trade/Device Name: Accuflow&AccuFlux Elastomeric Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: July 1, 2008
Received: July 3, 2008

Dear Mr. Lehtonen:

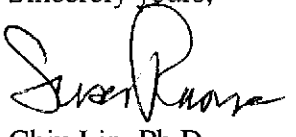
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-***[See Below For Phone Numbers]***. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081905

Device Name: Accuflow& AccuFLux Elastomeric Infusion Pump

Indications for Use:

AccuFlo & AccuFlux devices are intended for patients requiring intravenous, percutaneous, subcutaneous, intra-operative sites or epidural administration of medications. It is the responsibility of the user to ensure that the medication is prepared and administered accordance with the drug manufacturer's package insert. The devices deliver controlled amounts of medication directly to the intraoperative site for pain management and or antibiotic administration. The devices infuse the medication at an hourly flow rate. Medications are infused intraoperatively and postoperatively through intramuscular or subcutaneous routes.

The devices are also intended for controlled delivery of local anesthetics in close proximity to nerves for post operative regional anesthesia and pain management. Routes of administration may be intraoperative or percutaneous.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081905